510(k) Summary

NOV 2 2012

For

Kitazato IUI Catheters – K112396

1. **Submission Sponsor**

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3. **Date Prepared**

30 October 2012

4. **Device Name**

Trade/Proprietary Name:	Kitazato IUI Catheter with Stainless Steel Center Core Type, 10 cm, model number Type 1-v1 Kitazato IUI Catheter with Stainless Steel Center Core Type, 7 cm, model number Type 1-v2 Kitazato IUI Catheter without Stainless Steel Center Core Type, 10 cm, model number Type 2-v1 Kitazato IUI Catheter without Stainless Steel Center Core Type, 7 cm, model number Type 2-v2
Common/Usual Name:	Kitazato Intrauterine Insemination (IUI) Catheter
Classification Name:	Assisted Reproduction Catheter
Classification Regulation:	884.6110
Classification Panel:	Obstetrics/Gynecology

Product Code: MQF
Device Class: II

5. Predicate Devices

Gynetics Medical Products N.V. – Smooze Model 4225 – K013501

6. Indication for Use

Kitazato IUI Catheters consist of the following versions:

- Kitazato IUI Catheter with Stainless Steel Core Type, 10 cm, model number Type 1-v1
- Kitazato IUI Catheter with Stainless Steel Core Type, 7 cm, model number Type 1-v2
- Kitazato IUI Catheter without Stainless Steel Core Type, 10 cm, model number Type 2-v1
- Kitazato IUI Catheter without Stainless Steel Core Type, 7 cm, model number Type 2-v2

Kitazato IUI Catheters are used for the introduction of washed spermatozoa into the uterine cavity through the cervix.

7. Device Description

Kitazato IUI Catheters are sterile, single-use catheters for use in infusion of washed spermatozoa into the uterine cavity. Catheters are composed of a catheter shaft and a connector. The connector is connected to a syringe (not included with the catheter), and washed spermatozoa are aspirated through the tip of the catheter shaft connected to the syringe. During the insemination procedure, the shaft of catheter is introduced into the uterine cavity through the cervix, and then spermatozoa are injected into the uterine cavity.

The Kitazato IUI Catheter has the following types; IUI Catheter with Stainless Steel Center Core Type and IUI Catheter without Stainless Steel Center Core Type.

IUI Catheter with Stainless Steel Center Core Type: Catheters of this type consist of a catheter body and the connector. The rounded tip of the catheter shaft has a side hole used for aspiration and delivery of sperm. These catheters incorporate a stainless steel core in the center of the catheter shaft to provide rigidity to the catheter during device placement procedures. The connector has a 6% taper that allows it to be coupled with a standard syringe. One model is offered with the shaft of the catheter containing a depth mark and a stopper that aids in setting catheter insertion depth.

Model	Trade Name	Catheter Body	Catheter Length	Outer Diameter	Depth Mark	Stopper
Type1 -v1	IUI Catheter with Stainless Steel Center Core Type	12 Nylon	10 cm	1.65 mm / 5 Fr	Yes @ 7 cm	Yes
Type1 –v2	IUI Catheter with Stainless Steel Center Core Type	12 Nylon	7 cm	1.65 mm / 5 Fr	No	No

IUI Catheter without Stainless Steel Center Core Type: Catheters of this type consist of a catheter body and the connector. The rounded tip of the catheter shaft has a side hole used for aspiration and delivery of sperm. These catheters do not include a stainless steel center core in the body of the catheter. The connector has a 6% taper that allows it to be coupled with a standard syringe. One model is offered with the shaft of the catheter containing a depth mark and a stopper that aids in setting catheter insertion depth.

Model	Trade Name	Catheter Body	Catheter Length	Outer Diameter	Depth Mark	Stopper
Type2 -v1	IUI Catheter without Stainless Steel Center Core Type	12 Nylon	10cm	1.65 mm / 5 Fr	Yes @ 7 cm	Yes
Type2 -v2	IUI Catheter without Stainless Steel Center Core Type	12 Nylon	7cm	1.65 mm / 5 Fr	No	No

Comparison Table – Kitazato IUI Catheter with Stainless Steel Center Core, 10 cm, Type 1-v1

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter with Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
510(k) Number	K112396	K013501	N/A
Product Code	MQF	MQF	Same
Regulation Number	884.6110	884.6110	Same
Regulation Name	Assisted Reproduction Catheter	Assisted Reproduction Catheter	Same
Indications for use:	The Kitazato IUI Catheter with Stainless Steel Center Core is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	The Intra-Uterine Insemination Cannula is to be used for intra uterine artificial insemination procedures utilizing washed spermatozoa.	Same
Overall Design	The device consists of Catheter with Stainless Steel Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	The device consists of Catheter without Stainless Steel Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	There are slight differences that are discussed; the stainless steel core is to add rigidity for the catheter to assist if the uterine cervix is curved. This does not impact the use of the device and adds no safety or efficacy concerns as the Stainless Center Core is inside the catheter similar to the function of a stylet that is commonly used with invasive catheters.
Sterile	Radiation	Radiation	Same
Single-Use	Yes	Yes	Same
French Size	1.65 mm (5 Fr)	2 mm (6 Fr)	These have similar size outer diameter of catheter; the size difference of 0.35 mm or one French size does not

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter with Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
			impact the use of the device and adds no safety or efficacy concerns.
Length	10 cm	7 cm, 14 cm, 20 cm	The length of the Kitazato IUI catheter is within the range of the predicate device.
Depth Marks	Reference mark is located at 7 cm from tip	No Depth Mark	The mark at 7 cm from the tip is used as a reference point; the physician measures the length of uterus prior to insertion of the catheter and the mark is used as a guide. This does not impact the use of the device and adds no safety or efficacy concerns.
Tip	Closed and smoothly rounded; one side hole end type	Closed and smoothly rounded; one side hole end type	Same
Stylet	No; inner stainless steel center core	No	The stainless steel core is to add rigidity for the catheter to assist if the uterine cervix is curved. This does not impact the use of the device and adds no safety or efficacy concerns as the Stainless Steel Center Core is inside the catheter similar to the function of a stylet that is commonly used with invasive catheters.
Stopper	Yes	No	The stopper is used as a reference point; the physician measures the length of uterus prior to insertion of the catheter and utilizes the stopper as a guide. This does not impact the use of the device and adds no safety or efficacy concerns.

Comparison Table – Kitazato IUI Catheter with Stainless Steel Center Core, 7 cm, Type 1-v2

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter with Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
510(k) Number	K112396	K013501	N/A
Product Code	MQF	MQF	Same
Regulation Number	884.6110	884.6110	Same
Regulation Name	Assisted Reproduction Catheter	Assisted Reproduction Catheter	Same
Indications for use:	The Kitazato IUI Catheter with Stainless Steel Center Core is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	The Intra-Uterine Insemination Cannula is to be used for intra uterine artificial insemination procedures utilizing washed spermatozoa.	Same
Overall Design	The device consists of Catheter with Stainless Steel Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	The device consists of Catheter without Stainless Steel Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	There are slight differences that are discussed; the stainless steel core is to add rigidity for the catheter to assist if the uterine cervix is curved. This does not impact the use of the device and adds no safety or efficacy concerns as the Stainless Steel Center Core is inside the catheter similar to the function of a stylet that is commonly used with invasive catheters.
Sterile	Radiation	Radiation	Same
Single-Use	Yes	Yes	Same
French Size	1.65 mm (5 Fr)	2 mm (6 Fr)	These have similar size outer diameter of catheter; the size difference of 0.35 mm or one French size does not impact the use of the device and adds no safety or efficacy concerns.
Length	7 cm	7 cm, 14 cm, 20 cm	The length of the Kitazato IUI catheter is within the range of the predicate device.
Depth Marks	No Depth Mark	No Depth Mark	Same
Tip	Closed and smoothly rounded; one side hole end type	Closed and smoothly rounded; one side hole end type	Same
Stylet	No; inner stainless steel center core	No	The stainless steel core is to add rigidity for the catheter to assist if the uterine cervix is curved. This does not impact the use of the device and adds no safety or efficacy concerns as the

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter with Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
			Stainless Steel Center Core is inside the catheter similar to the function of a stylet that is commonly used with invasive catheters.
Stopper	No	No	Same

Comparison Table – Kitazato IUI Catheter without Stainless Steel Center Core Type, 10 cm, Type 2-v1

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter without Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
510(k) Number	K112396	K013501	N/A
Product Code	MQF	MQF	Same
Regulation Number	884.6110	884.6110	Same
Regulation Name	Assisted Reproduction Catheter	Assisted Reproduction Catheter	Same
Indications for use:	The Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	The Intra-Uterine Insemination Cannula is to be used for intra uterine artificial insemination procedures utilizing washed spermatozoa	Same
Overall Design	The device consists of Catheter without Stainless Steel Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	The device consists of Catheter without Stainless Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	Same
Sterile	Radiation	Radiation	Same
Single-Use	Yes	Yes	Same
French Size	1.65 mm (5 Fr)	2 mm (6 Fr)	These have similar size outer diameter of catheter; the size difference of 0.35 mm or one French size does not impact the use of the device and adds no safety or efficacy concerns.

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter without Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
Length	10 cm	7 cm, 14 cm, 20 cm	The length of the Kitazato IUI catheter is within the range of the predicate device.
Depth Marks	Reference mark is located at 7 cm from tip	No Depth Mark	The mark at 7 cm from the tip is used as a reference point; the physician measures the length of uterus prior to insertion of the catheter and the mark is used as a guide. This does not impact the use of the device and adds no safety or efficacy concerns.
Tip	Closed and smoothly rounded; one side hole end type	Closed and smoothly rounded; one side hole end type	Same
Stylet	No	No	Same
Stopper	Yes	No	The stopper is used as a reference point; the physician measures the length of uterus prior to insertion of the catheter and utilizes the stopper as a guide. This does not impact the use of the device and adds no safety or efficacy concerns.

Comparison Table – Kitazato IUI Catheter without Stainless Steel Center Core Type, 7 cm, Type 2-v2

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter without Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
510(k) Number	K112396	K013501	N/A
Product Code	MQF	MQF	Same
Regulation Number	884.6110	884.6110	Same
Regulation Name	Assisted Reproduction Catheter	Assisted Reproduction Catheter	Same
Indications for use:	The Kitazato IUI Catheter is used for the introduction of washed spermatozoa into the uterine cavity through the cervix.	The Intra-Uterine Insemination Cannula is to be used for intra uterine artificial insemination procedures utilizing washed spermatozoa	Same
Overall Design	The device consists of Catheter without Stainless Steel Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the	The device consists of Catheter without Stainless Center Core. The catheters are packaged in a barrier sterilization pouch /wrapping. A syringe is not included in the products.	Same

Manufacturer	KITAZATO Medical Co., Ltd.	Gynetics Medical Products NV	Kitazato IUI Catheter Comparison to Predicate
Trade Name	Kitazato IUI Catheter without Stainless Steel Center Core	Intra-Uterine Insemination and GIFT Catheters, Smooze #4225	
	products.		
Sterile	Radiation	Radiation	Same
Single-Use	Yes	Yes	Same
French Size	1.65 mm (5 Fr)	2 mm (6 Fr)	These have similar size outer diameter of catheter; the size difference of 0.35 mm or one French size does not impact the use of the device and adds no safety or efficacy concerns.
Length	7 cm	7 cm, 14 cm, 20 cm	The length of the Kitazato IUI catheter is within the range of the predicate device.
Depth Marks	No Depth Mark	No Depth Mark	Same
Tip	Closed and smoothly rounded; one side hole end type	Closed and smoothly rounded; one side hole end type	Same
Stylet	No	No	Same
Stopper	No	No	Same

8. Technological Characteristics

The indication for use and technology of the Kitazato IUI Catheters is substantially equivalent to the identified predicate devices.

9. Non-Clinical Testing

The catheter mechanical tensile testing, dimension testing, endotoxin testing, sterility testing and Human Sperm Survival Assay results support that all the specifications have met the acceptance criteria for the device.

- Mechanical Tensile Testing: Tensile strength to withstand 4.9N
- Dimensional Testing: Passes outer diameter and length according to specifications
- Endotoxin Testing: Endotoxin values conform to the value ≤20 EU/device
- Sterility Testing: No microbial growth from sterility testing
- Human Sperm Survival Assay: ≥70% motility at 24 hours

The Kitazato IUI Catheters passed all testing and supports the claims of substantial equivalence and safe operation.

The Kitazato IUI Catheters complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The substantial equivalence of the device is supported by the non-clinical testing. The validation testing of the device biocompatibility and HSSA testing was found to be acceptable and supports the claims of substantial equivalence.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that any differences between the Kitazato IUI Catheters and the predicate device do not raise any questions regarding its safety and effectiveness. The Kitazato IUI Catheters, as designed and manufactured, are substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Date: November 2, 2012

KITAZATO Medical Co., Ltd.
% Mr. Richard Vincins, CQA, CBA, RAC (US, EU)
Vice President, QA
Emergo Group, Inc.
611 West 5th Street, Third Floor
AUSTIN TX 78701

Re: K112396
Trade/Device Name: Kitazato IUI Catheter with Stainless Steel Core Type, 10 cm, model number Type 1-v1 and 7 cm, model number Type 1-v2
Kitazato IUI Catheter without Stainless Steel Core Type, 10 cm, model number Type 2-v1 and 7 cm, model number Type 2-v2
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted reproduction catheters
Regulatory Class: II
Product Code: MQF
Dated: October 22, 2012
Received: October 22, 2012

Dear Mr. Vincins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112396

Device Name: Kitazato IUI Catheter

Indications for Use:

Kitazato IUI Catheters consist of the following versions:

- Kitazato IUI Catheter with Stainless Steel Core Type, 10 cm, model number Type 1-v1
- Kitazato IUI Catheter with Stainless Steel Core Type, 7 cm, model number Type 1-v2
- Kitazato IUI Catheter without Stainless Steel Core Type, 10 cm, model number Type 2-v1
- Kitazato IUI Catheter without Stainless Steel Core Type, 7 cm, model number Type 2-v2

Kitazato IUI Catheters are used for the introduction of washed spermatozoa into the uterine cavity through the cervix.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2012.11.02 16:12:25 -04'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112396